REGULATORY GUIDE B2

COMPLYING WITH TITLE B - MEDICAL FACILITIES

South Carolina Department of Health
and Environmental Control

October 12, 2004

TABLE OF CONTENTS

Each medical facility that is registered with the Department is required to comply with Regulations 61-64, X-Rays (Title B), which are the regulations concerning x-ray equipment. This guide is intended to assist the medical facility in complying with Title B regulations.

FACILITY REGISTRATION APPROVAL (See RHB 2.4)

Prior to installation the facility must submit the following information to the Department:

- Facility name, location address, and mailing address.
- The name of the Radiation Safety Officer (RSO), who is responsible for radiation protection, and the individual's qualifications to serve in this capacity.
- Type and make of x-ray equipment to be installed.
- Operating policies and procedures. See below under "Operating Procedures".
- A training plan. To include operator certification by the South Carolina Quality Standards Association and facility specific training. See below under "Training".
- A shielding plan, if required.
- Shielding review fees must accompany the shielding plan.
- There is a $62.50 non-refundable fee required for registration of new facilities. The application fee must be submitted with the facility registration approval request. The $62.50 should be sent in the form of a check or money order made out to SCDHEC.

After review and approval of this information and receipt of application and shielding review fees, the Department will issue a Facility Registration Approval.

REGISTERING EQUIPMENT (See RHB 2.5)

All x-ray equipment is required to be registered with the Department. See Regulatory Guide B1 for assistance in registering equipment. The registrant is also required to report, in writing, any changes that affect his x-ray facility or the x-ray equipment. This includes change of location or mailing address, acquiring or disposing of x-ray equipment, changes in operating procedures that may affect an approved shielding plan, and any changes in the approved training plan or operating procedures.

REQUIREMENTS FOR OPERATING PROCEDURES (See RHB 4.2.4)

All facilities are required to have written operating procedures available to all x-ray operators. It is the responsibility of the registrant to ensure that each operator is familiar with the procedures and competent to operate the x-ray equipment. Documentation must be maintained indicating that each operator has read and agrees to adhere to the operating procedures. The procedures must include the following items, as a minimum:

1) **Policies and Procedures for Patient Holding.** The procedures must state whether or not, as a matter of policy, patients and/or films will be held at that facility. The availability and use of restraining devices must be addressed. The procedures must indicate the individual projections where mechanical holding devices cannot be used, and a human holder is required. The process to select a human holder must be documented, as well as the procedures that the human holder is to follow. Whenever possible, an adult

accompanying the patient should be used for holding. Pregnant females should not be used to hold a patient. Methods for protecting the human holder, such as wearing aprons and gloves, must be included. If a facility is required to routinely hold patients and/or films, then procedures to ensure that no one person is used routinely to hold patients must be included. If an employee may be required to hold patients or films more than three times a quarter, then the procedures must also address personnel monitoring of human holders.

The lead aprons and gloves must be checked annually for cracks and holes that could compromise the radiation protection they provide. This testing must be documented. Records of this testing must be kept for two years or until the next Department inspection.

2) **Policies and Procedures for Pregnant Workers**. Procedures to be followed when a worker declares her pregnancy must be included, as well as methods of informing workers of the total exposure received during gestation. If a facility has policies to change the work assignments of pregnant workers, then those policies should be stated. The Nuclear Regulatory Commission's Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers. This guide is available from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, D.C. 20013-7082.

3) **Policies and Procedures Regarding the Use of Gonadal Shielding.** Documentation must be included on when gonadal shielding will be used as a matter of policy. If gonadal shielding interferes with individual projections, then those projections should be specified. The proper use and placement of gonadal shielding must be addressed.

4) **Policies and Procedures for Pregnant Patients.** The procedures must include methods for determining possible patient pregnancy. Prescription of x-ray examinations of pregnant or possibly pregnant patients shall assure that medical consideration has been given to possible fetal exposure and appropriate measures are taken. X-ray techniques for minimizing fetal exposure must be included. Methods of determining fetal exposure and procedures to follow for advising the woman and her practitioner of the exposure received by the fetus must be included.

5) **Policies and Procedures for Personnel Monitoring.** The operating procedures must state whether or not personnel monitoring devices will be used at the facility. The procedures must tell employees how to correctly use personnel monitoring devices and how to care for personnel monitoring devices. The name of the person responsible for distribution, collection, and records of badges must be stated. The location of control badges must be given. The policies for reporting and investigating over-exposures must be stated. A prohibition against intentionally exposing any control or personnel badge must be included. Procedures must also be included instructing workers on how they may obtain the results from the monitoring.

6) **Procedures for Training New Employees.** See below under "Training." The procedures must include a statement indicating that all operators, other than licensed practitioners, will be certified by the South Carolina Radiation Quality Standards Association (SCRQSA). For more information, contact the SCRQSA at (803)771-6141.

7) **Methods for Quality Assurance.** The procedures must state the methods that the facility will use to assure that they are producing quality radiographs. This may vary widely from facility to facility. At a minimum, three items must be addressed in the quality assurance plan. These are (a) Equipment Performance tests of the x-ray system (b) a repeat analysis program and (c) standards for processing.

See below under "Quality Assurance."

PERSONNEL MONITORING (See RHB 3.12)

Personnel monitoring is required in the following situations:

1) When an employee is likely to receive greater than 10% of their occupational dose limit for one year.

2) When an employee under 18 years of age is likely to receive greater than 10% of their occupational dose limit for one year.

3) When an employee may be required to hold patients or films more than three times in a quarter.

4) When an individual enters a high radiation area.

5) All operators of mobile or portable x-ray equipment.

6) Declared pregnant workers who request an additional badge for monitoring doses underneath lead aprons.

7) When the Department deems that it is necessary.

The Department recommends instituting a personnel monitoring system for a period of at least one year to ensure that all individuals entering a restricted area do not receive a dose which would require personnel monitoring. If procedures require an individual's extremities to be in or near the primary beam, then ring badges should also be used. After monitoring for a year, if the doses received are well below 10 percent of the allowable exposure limits, the monitoring may be discontinued. The monitoring should be reinstated if new procedures are added, if the x-ray workload increases, if new employees are given x-ray duties, or after any changes that may affect the doses received. The records from monitoring must be retained indefinitely, even if the service is discontinued.

When a protective lead apron is worn by the operator, and a personnel monitoring device is used, the monitoring device must be worn at the collar outside of the apron. When two monitoring devices are worn (one outside and one under the apron) the one outside will be considered the permanent record for the individual. The Department may give consideration for the use of protective apparel provided that the registrant submits written procedures to ensure that this apparel is worn at all times. Written procedures must be submitted to and approved by the Department prior to the badge under the apron being used as the permanent record.

The personnel monitoring devices used to determine compliance with occupational dose limits must be processed by a vendor which possesses current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology (NIST). The accreditation must be for the type of radiation for which the individual wearing the device is monitored.

Each registrant must maintain records showing the radiation exposure for each person that is required to be monitored. The records must be preserved indefinitely, or until the Department authorizes their disposal. The records may be maintained on microfilm.

PRIOR OCCUPATIONAL EXPOSURE (See RHB 3.20)

Each registrant has the responsibility to require an employee to disclose their previous occupational dose prior to

working at the registrant's facility. The registrant must obtain a written, signed statement that states either that the worker had no prior occupational dose during the current calendar quarter or states the nature and amount of any prior occupational dose during the current calendar quarter. For the purpose of this statement, the current calendar quarter is interpreted to mean the most recently available calendar quarter. The registrant must maintain these written statements until the Department authorizes their disposition.

OCCUPATIONAL EXPOSURE AT MULTIPLE FACILITIES (See RHB 3.4.4)

If an employee is likely to receive a dose in excess of 50% of the annual allowable dose, the exposure that an employee receives at any facility must be recorded by each facility at which the employee works. The simplest way to achieve compliance with this requirement would be for an employee to be provided with a monitor to be worn at all facilities where employment occurs, and an individual monitor issued by each facility. Then, total occupational dose could be tracked, as well as doses received at individual facilities.

TRAINING (See RHB 4.2.3)

Each medical facility is required by RHB 4.2.3 to ensure that all x-ray operators possess a current, valid certificate from the South Carolina Radiation Quality Standards Association (SCRQSA). Each operator's current certificate must be displayed in public view. Other methods of display may be acceptable. Contact the Department for approval. Licensed practitioners (physicians, chiropractors, podiatrists, etc.) are exempt from the certification requirements.

An operator is defined as one who applies ionizing radiation to humans for diagnostic or therapeutic purposes. An operator also includes anyone who performs x-ray exam setups, patient positioning, technique selection, therapy treatment setups, setting of treatment parameters, verification of treatment accessories, or documents daily treatments for a patient's chart.

Each operator, including physicians, is also required to receive training specific to the equipment and procedures in use at the facility, including machine specific training, use of personnel monitoring devices, quality assurance procedures, and the operating procedures required by RHB 4.2.4. This training must be documented for each operator and maintained at the facility. For new employees, this training must begin within 30 days after employment.

The training records will be checked as part of the routine inspection by the Department. In addition, the Department may request at any time to review the training records of an employee.

QUALITY ASSURANCE (See RHB 4.2.18)

The following items should be checked, at a minimum, for the Department to consider the quality assurance program acceptable. These items are not inclusive of all items that could be addressed in a quality assurance program. Quality assurance programs vary widely from facility to facility, and it is each registrant's responsibility to evaluate the performance of their x-ray imaging systems and tailor their quality assurance plan accordingly. Employees of the facility may or may not be the individuals carrying out the quality assurance monitoring listed below. In most facilities, the quality assurance testing will probably be performed by a combination of the facility and an x-ray vendor. A facility that chooses to have an x-ray vendor perform some or all of the quality assurance monitoring must use a vendor that is registered with DHEC to provide those services. A list of registered vendors is available from the

Department.

The following items should be contained in the quality assurance manual, as appropriate:

1) A list of the parameters to be monitored, the frequency of monitoring, and the limits that require corrective action to be taken.

2) A description of the procedures to be used for monitoring each parameter.

3) Procedures to be followed to call problems to the attention of those responsible for correcting them.

4) A list of the records, along with sample forms, that the facility is using. Notations should be made concerning the length of time that each type of record is kept before discarding.

5) Results of acceptance testing of new equipment.

As stated above, the three items that must be addressed in a quality assurance plan are (1) equipment performance tests (initial or annual calibrations) of the x-ray system, (2) a repeat analysis program, and (3) standards for processing.

1) **Equipment Performance Tests of the X-ray System and Associated Components (Calibrations).** Written standards must be established for the proper performance of each x-ray imaging system under the registrant's control. Routine testing must be carried out on an annual basis, at a minimum, to ensure accordance with the standards. Some x-ray units, because of their high workload, may require testing more frequently. Equipment performance tests must include numerical data. Items found to be non-compliant during these tests must be corrected within sixty (60) days of receipt of the report. Records showing the test results and the correction of non-compliant items found must be retained for five years. If a portable unit is returned to the manufacturer, the unit must be tested once it is returned to the facility. Testing completed prior to return shipment to the facility will not be acceptable.

The following items, as appropriate, should be included in the x-ray system standards for radiographic equipment. Items marked with an asterisk (*) indicate that this item may be tested by the vendor or the facility.

- Half-value layer (HVL)
- X-ray field/light field alignment
- Exposure reproducibility
- mA/mAs linearity
- kVp accuracy
- Timer reproducibility and accuracy
- X-ray beam/image receptor centering
- Collimator light illuminance
- Actual vs. indicated collimator field sizes
- Positive beam limitation function, if provided
- Visual and audible indication of exposure
- Capacitor discharge radiation levels, if appropriate
- Minimum field size
- Patient exposure at skin entrance, for most common exams performed at the facility
- Proper function of automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time

- Grid uniformity and alignment
- Integrity of lead aprons, gloves, and other protective clothing *****
- Screen/film contact *****
- Actual vs. Indicated Source to Image Distance (SID), for all clinically used SIDs
- Beam size(s) for fixed collimation, if applicable

These items must be checked upon initial installation and after any maintenance or repair that could affect their status:

- Adherence to the approved shielding plan (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)
- Minimum source to skin distance on mobile radiographic units
- Proper indication of multiple tubes on units so equipped

The following items, as appropriate, should be included in the x-ray system standards for fluoroscopic equipment. Items marked with an asterisk (*****) indicate that this item may be tested by the vendor or the facility.

- X-ray beam/Viewed image size comparison
- Exposure rate output measurement, using average techniques, using maximum techniques, and in high level exposure mode, if so equipped, in each mode routinely used
- Image intensifier interlock with unit in park position
- Primary barrier transmission
- Cumulative timer function
- Measurement of scattered radiation
- High contrast resolution and low contrast performance
- Spot film beam size
- Spot film beam centering
- Spot film exposure reproducibility
- Spot film mA/mAs linearity
- Spot film timer reproducibility and accuracy
- Proper function of spot film automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time
- kVp accuracy
- Half-value layer (HVL)
- Cinefluorographic exposure rates
- Integrity of lead aprons, gloves, and other protective clothing *****
- Intergrity of bucky slot cover shielding and lead drapes *****
- Continuous indication of kV and mA during fluoroscopy

These items must be checked upon initial installation and after any maintenance or repair that could affect their status:

- Adherence to the approved shielding plan (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)
- Minimum source to skin distance

The following items, as appropriate, should be included in the x-ray system standard for Computed Tomography (CT) units (including CT treatment planning systems used in radiation therapy). Items marked with an asterisk (*****) indicate that this item may be tested by the vendor or the facility.

- Actual vs. indicated scan increment

- Measurement of radiation output(patient dose) (CT treatment planning systems are exempt)
- CT number calibration and constancy
- High and low contrast resolution
- Precision (noise)
- Contrast scale
- Spot checks as specified by a Class IX Vendor
- An area survey, upon initial installation
- Integrity of lead aprons, gloves, and other protective clothing *****

These items must be checked upon initial installation and after any maintenance or repair that could affect their status:

- Adherence to the approved shielding plan (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)

2) **Repeat analysis program.** An on-going retake analysis program can provide information about existing problems in a radiology department. A retake is defined as any radiograph that had to be done over, re-exposing the patient to radiation, because of some error, breakdown, or degradation in the radiographic process.

Each registrant must establish a repeat analysis program, with the following frequency:

- For facilities that produce less than 250 radiographs per month, the repeat analysis must be done monthly.
- For facilities that produce more than 250 radiographs per month, the repeat analysis must be done weekly or the period of time that it takes to produce about 1000 radiographs, whichever comes first.

The analysis must include at a minimum the overall repeat rate and the cause for repeats. The cause for repeats may include patient positioning, patient motion, radiographs too light or too dark, artifacts, fog, and processor problems.

3) **Standards for Processing.** The following items should be checked as components of the final diagnostic image obtained. Again, these items are not all inclusive, and should be tailored to meet the individual facility conditions.

a) Evaluation of screens, cassettes, and grids. Procedures should be included for cleaning and maintenance of cassettes and screens and checks of screen condition. Documentation of the cleanings must be kept for 2 years or until the next inspection by this Department.

b) Processor quality assurance. The quality assurance plan should address the care, maintenance, and cleaning of the processor, temperature measurement, replenishment rates, water flow rates, and residual fixer testing. Records of processor maintenance must be kept for 2 years or until the next inspection by this Department. Facilities that process more than 250 films per week must also evaluate processor variability by use of a sensitometer and densitometer. Control limits for each parameter must be monitored. Action must be taken when the control limits are exceeded. Documentation of densitometry and sensitometry must be maintained for 2 years or until the next inspection by this Department. The frequency must be as follows:

- For facilities that process more than 250 films per day, testing must be performed daily (each day examinations are performed) before clinical films are processed.
- For facilities that process less than 250 films per day but more than 250 films per week,

testing must be performed on a weekly basis, at a minimum.
- Facilities that operate 24 hours per day must perform the required testing once each day.

c) Evaluation of darkroom and film. Film base plus fog should be tested, along with darkroom fog conditions. Darkrooms must be "light tight" to the dark adapted eye, and should be free from dust and dirt. The darkroom must have a functional safelight.

For new facilities, the quality assurance plan will be reviewed by the Department before registration of the x-ray equipment. For existing facilities, the quality assurance plan will be reviewed at the first inspection after the effective date of the regulations. For all facilities, records of quality assurance testing and monitoring will be reviewed on each inspection conducted. Facilities must maintain records of all testing and checks performed.

SHIELDING PLANS (See RHB 4.4)

Before construction, a facility is required to submit a radiation shielding plan and a shielding review fee to the Department for review and approval. The shielding plan must be reviewed by a Class III or a Class IV vendor. After the equipment is installed, "as-built" drawings and the area survey (if applicable) are required to be submitted. See Regulatory Guide B6 for assistance. The shielding plan must be accompanied by a $62.50 Shielding Plan Review fee.

MANUAL FILM PROCESSING (See RHB 4.2.19.1)

When a facility performs manual film processing, the following items are required to be used by the facility:

1) Processing tanks that are mechanically rigid and corrosion resistant.
2) A dedicated darkroom thermometer to measure developer temperature. Developer temperature must be within 60° F and 80° F (16° C to 27° C).
3) A dedicated darkroom timer to set film processing time.
4) Documentation to show when the film processing chemicals are changed.
5) A functional darkroom safelight compatible with the type of film being used.
6) A time-temperature developing chart.

SIGHT DEVELOPING OF RADIOGRAPHS IS NOT ACCEPTABLE FOR PROCESSING FILMS.
The film manufacturer or a vendor registered with the Department should be able to assist facilities in obtaining the items listed above.

AUTOMATIC FILM PROCESSING (See RHB 4.2.19.2)

When a facility uses an automatic processor or other closed processing system, the following items are required:

1) Processing chemical temperatures consistent with the type of film(s) being processed.
2) Appropriate film processing chemicals and replenishment rates.
3) A functional darkroom safelight compatible with the type of film(s) being used.
4) Film immersion times consistent with the developer temperature.
5) The specified developer temperature must be immediately available.

The film manufacturer or a vendor registered with the Department should be able to assist facilities in obtaining the items listed above.

OTHER FILM PROCESSING REQUIREMENTS (See RHB 4.2.19.3)

Film pass boxes must be "light-tight" and incorporate adequate shielding to prevent fogging of undeveloped film from stray radiation. Film must be stored in a cool, dry place protected from stray radiation. Film in open packages must be stored in a "light tight" container. Film should not be stored where it can be exposed to chemical fumes or radiation. Film that is expired or outdated shall not be used, unless it has been properly stored, and passes a sensitometric test for base + fog, and speed.

Film cassettes and intensifying screens must be inspected in accordance with the facility's approved operating procedures. They must be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality. Documentation of these inspections and cleanings must be maintained for 2 years or until the next inspection by this Department.

Film developing solutions should be properly stored; they should never be allowed to freeze. They must be prepared according to the directions given by the manufacturer, and maintained in strength by replenishment or renewal.

ADMINISTRATIVE REQUIREMENTS

The following items are required to be posted or present at x-ray facilities:

1) Radiation area signs. Each entrance into a radiation area must be posted with a radiation area sign. If it is a high radiation area, then it must be posted with a high radiation area sign. This includes any access from outside the room, such as a restroom, with an entrance from a hall and the x-ray room. (See RHB 3.16)

2) Technique charts. (See RHB 4.2.8) A technique chart must be posted at each control panel, which states the following information:

- The patient's body part and anatomical size versus technique factors to be used. For pediatric patients, the body part thickness versus age may be used.
- The type and size of film or the film-screen combination to be used.
- The source to image distance (SID) to be used.
- The type and location of placement of patient shielding (e.g., gonad, thyroid, etc.) to be used.
- For automatic exposure control systems, the appropriate exposure detector(s) must be specified. For automatic exposure control systems, there must also be available a technique chart to be used when the equipment is operated in a non-automatic mode.

3) A sign must be posted in a conspicuous area that notifies patients to inform the technologist if they are pregnant or might be pregnant. (See RHB 4.2.9)

4) The x-ray control must have a label on it which states "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed." (See RHB 4.3.1)

5) A patient log is required at each facility. The patient log must show the patient's name, the type of examination, and the dates the examinations were performed. When the patient or film is held by a human, then the name of the human holder must be recorded. When the examination is performed using any type of fluoroscopy, the logbook shall include an estimate of the amount of time that fluoroscopy was performed or the number of times that the cumulative timer was reset. (See RHB 4.2.17)

6) For fluoroscopic units, the results from periodic measurement of entrance exposure rates is required for each mode used clinically. The results must be posted where any fluoroscopist may have ready access to them while using the fluoroscope. The results shall be stated in Roentgens per minute and include the technique factors used to make the measurement. This must be tested and posted annually. The name of the person performing the measurements and the date the measurements were performed shall also be included. Any operational mode that is routinely used must be tested, and the results posted. This would include cine mode, ABC mode, etc. (See RHB 4.9.4.3.6)

MISADMINISTRATIONS (See RHB 1.11)

Misadministration means the administration of (1) radiation to the wrong patient (2) performance of a diagnostic or therapeutic procedure other than that ordered by a prescribing physician, (3) a therapeutic radiation dose from a source such that errors in the source calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than 20 percent, (4) a therapeutic radiation dose from a source such that errors in the source calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than 10 percent, when the treatment consists of three or fewer fractions, or (5) when the calculated weekly treatment dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose. Situations that would not constitute misadministration would include, for example, incorrect ordering of an exam, such as ordering a lateral chest x-ray when a PA chest x-ray was desired. Another example that is not misadministration would be if, after review of films from an exam, a radiologist who was not the original ordering physician decides that additional views are necessary to adequately image the area of interest. Repeat films performed due to patient motion, processing errors or problems, incorrect patient positioning, or improper radiographic technique selection are not considered misadministrations.

Each registrant must retain records of misadministrations. The record must contain the name of all individuals involved in the misadministration (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence. The records of misadministration must be maintained for three years for diagnostic misadministrations, and ten years for therapy misadministrations.

The action that a registrant must take in response to a misadministration depends on the type of misadministration that occurs. When a misadministration involves a diagnostic procedure, the registrant shall promptly investigate its cause, make a record for Department review, and maintain the records for three years.

OVEREXPOSURES (See RHB 3.25)

The registrant is required to report to the Department any exposure of an individual in excess of any limit in the regulations. The registrant is also required to report any radiation levels in an unrestricted area that are in excess of 10 times any limit in the regulations. The time frame for reporting overexposures depends on the exposure that an individual receives. Immediate, 24 hour, and/or thirty day written notification may be required. See RHB 3.25 concerning radiation levels and the requirements for reporting.

RECORDS

The registrant is required to maintain all records required to comply with or show compliance with Title B. These records include:

- Records showing receipt, transfer, use, storage, and disposal of all sources of radiation. (RHB 1.10.1)
- Records showing model and serial numbers of all tubes, controls, beam limiting devices, vertical cassette holders, and tables. (RHB 1.10.2.1)
- Tube rating charts and cooling curves. (RHB 1.10.2.2)
- Records of aluminum equivalent filtration of the useful beam for all x-ray units, including any routine variation. (RHB 1.10.2.3)
- Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system and components, with the names of persons who performed such services. (RHB 1.10.2.4)
- Copies of all correspondence with the Department. (RHB 1.10.2.5)
- Records of misadministrations. (RHB 1.11.2)
- Records of prior occupational dose for employees. (RHB 3.20)
- Records of personnel monitoring results. (RHB 3.22.1)
- Records of employee training. (RHB 4.2.3)
- X-ray logs. (RHB 4.2.17)
- Results of periodic equipment performance tests of x-ray equipment. (RHB 4.2.18)
- Repeat analysis records. (RHB 4.2.18.4)
- A scale drawing of the x-ray room showing occupancies of surrounding areas, and composition of all walls, or results of an area survey performed by a Class IX vendor showing radiation levels around the room. (RHB 4.4.3)
- Any other records of routine checks, quality control, or testing that are required to be carried out.

INSPECTIONS

The Department conducts routine periodic inspections of x-ray facilities, on a priority system based on the type of facility that is operating. The Department will also conduct inspections if a complaint is received, or if a facility requests an inspection. If violations are found on an inspection, a follow-up inspection may be conducted if the severity of the violations warrants it. The Department may also inspect newly installed, Food and Drug Administration (FDA) certified units for compliance with FDA regulations. Generally, the Department will send a Notice of Inspection letter to a facility about two weeks in advance of the inspection. Inspections by the Department are mandatory, but every attempt will be made to accommodate patient schedules. The Department does have the right to make unannounced inspections.

The inspection consists of checking the operation of the x-ray equipment, as well as checking administrative items such as records. Generally, an inspection requires use of the x-ray equipment for about one hour per control. The facility can greatly assist the Department inspector by using the attached inspection checklist to ensure that all records are available for review. The checklist also contains some questions that will be asked by the inspector. Having this information readily available at the time of inspection will greatly facilitate the inspection process.

After a facility is inspected, the inspector will conduct an exit interview. The inspector will discuss any items of noncompliance, as well as any other items that the inspector deems relevant. The inspector will leave an inspection report at the conclusion of the inspection. The inspection report will cite any violations of the regulations. The inspector may also make recommendations concerning the x-ray equipment or the facility itself. A facility representative must sign the inspection report acknowledging receipt of the report. All violations are required to be corrected within 60 days of the inspection.

There may be some inspections which may require additional information before they are completed. In these situations, the inspector will send a written report to the facility within approximately two weeks of the inspection. After receiving the report, the facility has twenty days to respond, in writing, to the Department. This twenty day notification must indicate that corrective action will be taken to correct any violations that were found upon inspection. The Department will respond, in writing, to the twenty day notification, and will give a date by which all corrections must be made. The facility must notify the Department, in writing, by this date that corrections have been made.

The facility has the option of correcting recommendations. Each violation and recommendation must be addressed individually. Corrective action must be described for each violation and recommendation. It will not suffice to simply state that all violations and recommendations have been corrected. If a facility chooses not to accept a recommendation made by the Department, the facility should state that in their response. After the Department has received the sixty day notification and reviewed the corrective action, a Completed Corrective Action letter will be sent to the facility.

QUESTIONS

If you have questions, please feel free to call or write:

S.C. DHEC
Bureau of Radiological Health
2600 Bull Street
Columbia, SC 29201
(803) 545-4400
FAX: (803) 545-4412

Regulatory Guides

B1 - Registration of X-ray Facilities and Equipment
B2 - Complying with Title B - Medical Facilities
B3 - Complying with Title B - Dental Facilities
B4 - Complying with Title B – Facilities Utilizing Industrial or Analytical Equipment
B5 - Vendor Registration and Responsibilities
B6 - Shielding Plans
B7 - Complying with Title B – Mammography
B8 – Complying with Title B - Bone Densitometers
B9 – Complying with Title B – Veterinary Facilities

Visit our web site at: www.scdhec.net

CHECKLIST FOR DHEC INSPECTION

Please have available the following records for the DHEC inspector:

_____ Personnel monitoring reports.

_____ Records of previous occupational dose for employees.

_____ Repeat analysis records.

_____ Patient logs.

_____ Documentation of operator training. (SCRQSA certificates and facility specific)

_____ Records from testing x-ray system performance, including calibration and service records, as well as in-house testing.

_____ Records from processing quality assurance program, including processor maintenance, cassette/screen cleanings, and densitometry/sensitometry.

_____ Misadministration records.

_____ A list of all operators of the x-ray equipment. This includes routine operators, as well as back-up operators and part-time operators. Indicate on the list the title of each operator, such as R.T., R.N., etc., and SCRQSA certificate number.

_____ Operating procedures. (Including Patient Holding, Pregnant Workers, Gonadal Shielding, Pregnant Patients, Personnel Monitoring, Training, Quality Assurance)

Please be familiar with, and be prepared to show the DHEC inspector the following items:

_____ Posted radiation area signs.
_____ Posted technique charts.
_____ Posted pregnancy posters.
_____ Posted measured fluoroscopic output rates.
_____ Posted "Notice to Employees"

Other questions the inspector will ask:

1) What brand, type, size, and speed of film do you use?
2) What brand and type of screens do you use?
3) Are films ever held during x-ray exams?
4) Are patients ever held during x-ray exams?
5) Who does servicing on the x-ray equipment?